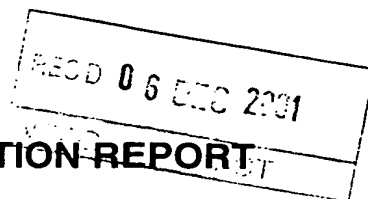




PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference SPG/P36102WO		FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/03377	International filing date (day/month/year) 04/09/2000	Priority date (day/month/year) 04/09/1999	
International Patent Classification (IPC) or national classification and IPC A61M15/00			
Applicant INNOVATA BIOMED LIMITED et al.			
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 14 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>			
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input checked="" type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input checked="" type="checkbox"/> Certain defects in the international applicationVIII <input type="checkbox"/> Certain observations on the international application			
Date of submission of the demand 02/04/2001		Date of completion of this report 04.12.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Krantz, L Telephone No. +49 89 2399 2523 	

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International application No. PCT/GB00/03377

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-10 as originally filed

Claims, No.:

1-32 as originally filed

Drawings, sheets:

1/10-10/10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

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☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
☒ the parts relating to claims Nos. 1 - 3.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims
	No:	Claims 1 , 2
Inventive step (IS)	Yes:	Claims
	No:	Claims 1 , 2

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Industrial applicability (IA) Yes: Claims 1 , 2
 No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

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The objection about lack of unity (see also section IV) was made in the search-report of 5 January 2001 and repeated by the examining-division on 19 July 2001.

Yet the Applicant has not restricted the many independent claims:
1 , 4 , 20 , 21 , 24 , 26 , 27 , 29 and 32
and neither has paid additional examination fees.

Therefore according to PCT-Article 34.3.c the present international preliminary examination report is issued
("If the applicant does not comply with the invitation ...
the International Preliminary Examination Authority shall establish
an international preliminary examination report ...")

Therefore according to PCT-Article 34.3 this report deals with those parts of the application which APPEARS to be the main invention namely claims 1 - 3.

Merely as a guide to the Applicant for any national phase , there are also a few remarks about other claims and the description .

The examination is being carried out on the following application documents:

description pages 1 - 10 as originally filed

claims 1 - 32 " "

drawings 1/10 - 10/10 " "

The drawings and page 10 were filed in November and December 2000 but since this was before the demand for examination of 2 April 2001 these documents count as "originals" .

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The following documents cited in the International Search report will be referred to by means of the following appellation:

D1 : WO-A-92-3175

D2 : US-A-4 860 740

IV

Lack of unity :

The application is considered to claim (at least) two inventions :

Claim 1 defines a delivery-device where some metering-members containing an unknown material , rotate but are not necessarily in a magazine.

Independent claim 24 defines a magazine for some spools containing medicine. Thus the magazine of claim 24 does not contain metering-members but spools which may have another form than metering-members.

Furthermore the magazine may not be able to be used with the delivery-device of claim 1 , the magazine may have nothing to do with the delivery-device of claim 1 which may be for cement.

Further proofs for lack of unity under PCT-Rule 13 will be given below.

The reason that the examining-division mentions a lower number of independent inventions than the search-division is that some of the independent claims are considered to be so far away from the description , that they lack support in the description , Article 6 PCT and should be deleted.

Yet this may not prevent a search for such constructions.

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IV .2

General comment about lack of unity according to PCT-Rule 13 :

If an Applicant wishes to define his invention in several independent claims

Rule 13 requests that there are some features IN COMMON

between ALL independent claims (see also PCT-Guidelines C-III 4.4 :

ANY independent claim should contain ALL essential features)

and these features have to be novel.

Since the subject-matter of claim 1 is not new (see below) there is not one single new feature in claim 1 which could possibly be in common with other independent claims.

Also independent claim 24 lacks novelty , see below.

V

Claim 1 is not new over D1:

In D1 the metering-members are the capsules C positioned in a rotating magazine 4.

The rotation-axis of this magazine 4 is the cylindrical shaft 26 on which the magazine 4 is mounted see D1 page 7 line 6.

In D1 fig 1 the capsules C (= metering-member) fall down through hole 40 into a chamber see also D1 fig 2 near 8.

From this chamber the capsule is pushed horizontally by pushing-portion 56 into the center-chamber 12 (capsule emptying chamber 12 , P.6 L.24) and punctured by horizontally moving pins 60.

Thus the features of claim 1 of the invention are seen as follows in D1:

- rotatable metering-member C
- material delivery passage 26
- material delivery orifice 48 (mouthpiece 48)

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- actuator member 56 , 64
(material retaining position D1 fig 2)
- the actuator-member 56 moves radially to the rotation-axis 26 of the magazine 4 and pierces the capsule C (metering-member) with two radial holes.

The capsules in D1 ALSO move between two planes , but this is also possible in claim 1 of the invention as long as the two radial "actions" are present.

V .2

Claim 1 also lacks novelty over D2:

In D2 fig 3-a the user or patient opens the cover 28 , 31.

Then in D2 fig 3-b the user presses on latch-42 which will free a ledge-44 on extractor-23.

Due to spring-40 (D2 fig 1) this extractor-23 will automatically move up as seen in D2 fig 3-c and thereby pull up the top-14 of a medicine-capsule 12-14.

In a second half of this upwards movement the pawl-41 on spring-40 (D2 fig 1) will push a toothed-wheel-36 (D2 fig 2) and thereby turn by one step the round support-member-20 which is the magazine for the capsules 12-14.

By this one-step rotation the open capsule 12 (where the top-14 has already been pulled off by extractor-23) is rotated into opening 19 leading to mouthpiece 18 , this is the situation in D2 fig 3-d.

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Thus the features of claim 1 of the invention are seen as follows in D2:

- rotatable metering-member 12 - 14
- material delivery passage 19
- material delivery orifice 18 (mouthpiece 18)
- actuator member 23 + 40 + 41
(material retaining position D2 fig 3-b , the top-14 is still on the capsule 12-14)
- the actuator-member 23 moves radially to the rotation-axis 22 of the magazine 20 and actuates the capsule 12-14 (metering-member) by pulling off the top-14 in a radial direction D2 fig 3-c

V .3

Also dependent claim 2 lack novelty over D2:

In D2 there are several capsules (metering-members) in the rotating magazine 20.

V .4

Claim 3 is unclear. It is stated as a mere wish that the device can take up to a million magazines without giving any constructional details.

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V .5

Other claims:

Also independent claim 24 lacks novelty over D2:

If the capsules 12-14 in D2 are called spools (they can roll on a table just like the spools 2 of the invention) , they are radially mounted in magazine 20 in D2 and they are also radially "facing" ie. they will open in a radial direction and powder will come out in a radial direction, D2 fig 3-d. In a new claim for a magazine , it should be specified where the "face" of a spool is , otherwise it is not possible to determine if a spool is "facing" anything.

Claims 30 and 31:

It is considered obvious to use ANY available dry medicine in the device and magazines of D1 and D2.
(there is no INHALER in claims 1 or 2 as alleged in claim 30).

VII

Ambiguities or other problems in the claims :

In claim 1 first line "rotatable" should be rotatable .

Claims 26 , 27 , 28 and 32 have not been searched and therefore will never be examined.

Claim 29 is not examined due to PCT-Rule 67.1.iv (therapy) .

The claims appended to each other should be grouped together see PCT-Rule 6.4.c

Therefore claim 19 should be moved forward near claim 2.

Claim 22 should be moved up after claim 17.

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The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Consistent terminology PCT-Rule 10.2 :

The same items should have the same names all over and not be called "spools" in some claims and "metering-members" in others. It is pointed out that infringement of a rule is sufficient to refuse an application in a national phase.

Independent claims being unclear or not supported by description :

Independent claim 4 is not supported by the description :

According to the description it is a basic principle of the invention that the device is FLAT , page 2 line 11:

"... a significantly slimmer device may be produced" .

This is obtained by letting the push-rod (moving the ampoules or metering-members or spools 2) move in the same plane as the other parts of the device , see page 2 line 6:

"... push rod lies in essentially the same plane ... axis of the spools lie in the same plane as the magazine"

All this is not in independent claim 4. Here the push-rod may be perpendicular to everything else in the device and does not move in any radial-direction as in claim 1.

Although the search-examiner has searched this claim namely devices with several magazines , the examining-division does not consider it justified that the Applicant (in a later national procedure) obtains protection for a device for which there is no embodiment given in the description . It is against PCT-Rule 5.1.a.v :

"The description shall ... set forth at least the best mode"

Therefore claims 5 - 18 , all appended to claim 4 , are not commented upon.

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Independent claim 20 is unclear.

If a man is told to walk in a RADIAL direction he naturally also will need information about where the CENTER (or rotation axis as in claim 1) is. There is no such information in claim 20, the metering-member is not even said to rotate.

Independent claim 21 is not supported by the description:

The problem is the same as in claim 4.

The push-rod may be perpendicular to anything else and although the magazine is said to rotate then the push-rod is not moving along a radius to the rotation-axis.

VII .2

Problems in the description:

The description should be adapted to new claims

Thus page 2 lines 15 - 22 are a word-by-word repetition of original claim 1.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description nor are these documents identified therein.

Page 8 line 22 "uppermost magazine 101-b" actually magazine 101-b is DOWN in figure 7.

P.8 L.29 "circumferential surface 112" there is no number 112 in any figure.

P.9 L.8 "The male member 11 is biased away from the magazine 101-a ..." In fig 9 the pin 11 points down into magazine 101-a.

P.9 L.13 119 is used for two different things a groove and a distal-end.

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The TITLE is not precise , PCT-Guidelines C-II 3.2

The title "device" does not give the public the slightest idea within which technical field the invention is (automobiles and toothbrushes are also devices)

It is noted that if the Applicant does not limit the claims to inhalators then additional searches may be necessary in a national phase.

See first lines of the description :

"This invention relates to a novel form of material delivery device ..."

This includes also rotating magazines for cement dispensers or for filling metered pouches of rice into food packages.

VII .3

The primary reason for lack of unity was given in the first communication to the Applicant of 19.7.2001 and is repeated in the present communication section IV and this reason necessitates NO comparison with prior art. Thus this reason belongs to "a priori" lack of unity according to the separation between "a priori" and "a posteriori" given in PCT-Guidelines C-III 7.5

According to PCT-Guidelines C-VI 5.3 iii the problem of lack of unity can be dealt with CONCURRENTLY with the first written opinion.

The first written opinion should deal with the relevant items under PCT-Rule 66.2.a (obviously not all of the items since amino-acids may not be present in all applications) .

In the first communication of 19.7.2001 ADDITIONALLY an extensive examination of novelty or clarity of several claims (claims 1 - 18 , 20 , 21 , 24 and 26 - 31) and of ambiguities in the description was given whereby the requirements of PCT-Rule 66.2.a for the contents of a first written opinion are met.

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Therefore a statement from the Applicant after the receipt of the first communication of 19.7.2001 that he looks forward to receive a written opinion cannot be complied with. Such a written opinion would not have had other contents than the first communication and thus would have been a superfluous repetition. With the first communication 19.7.2001 the Applicant received sufficiently information to reduce , restrict or amend the claims.

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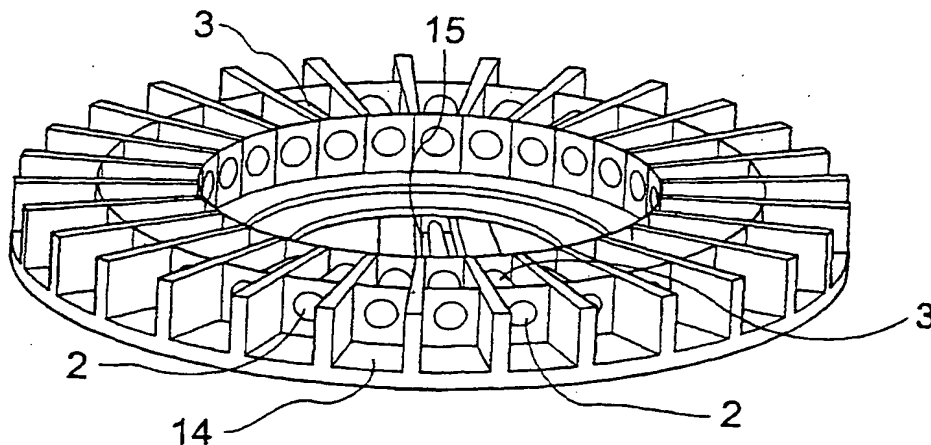
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Published:
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[Continued on next page]

(54) Title: DELIVERY DEVICE



(57) Abstract: A delivery device, e.g. an inhaler, comprises a rotatable metering member adapted to dispense a measured amount of material, a material delivery passage and a material delivery orifice and at least one actuator member adapted to move the metering member from a material retaining position to a material dispensing position. In a magazine comprising a plurality of metering members, the actuator and metering members may operate in a radial direction. A plurality of rotatable magazines may be utilised in the delivery device. The delivery device may be used to deliver a single or a combination therapy.

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— Before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

DELIVERY DEVICE

This invention relates to a novel form of material delivery device, for example, a medicament delivery device, such as an inhaler. In particular the invention provides
5 a novel form of dry powder inhaler and a method of delivering a medicament.

Dry powder inhalers are known, such as TECHNOHALER, being developed by Innovata Biomed in the UK. Such a device is described in International Patent Application No WO 93/16748 (PCT/GB93/00335). WO '748 describes an inhaler
10 which comprises a disc like magazine having a plurality of medicament carrying receptacles around its periphery. Each receptacle comprises a spool housed in a spool carrier. Each spool has a flange at each end which form a tight slidable fit within the body of the spool carrier. The space left between the body of the spool and the spool carrier is filled with an appropriate medicament.

15

The known TECHNOHALER is provided with suitable indexing means, including a push button and a ratchet mechanism which engages with the upper surface of the disc. Depression of the push button urges a push rod to push the spool, which is adjacent the inhalation passage of the inhaler, downwards and almost fully out of the
20 spool carrier, and into the inhalation passage. As the spool is pushed into the inhalation passage, it carries with it the measured quantity of medicament which it has been used to contain inside the magazine. The user can then inhale through the mouthpiece so as to take up the drug now released into the inhalation passage. The upper flange of the spool remains, however, held by the lower part of the receptacle.

25 When the user then releases push button, the ratchet mechanism causes the disc to rotate by one step so that the next receptacle is brought into register with the inhalation passage. The inhaler is thus reset and ready for delivery of another dose of drug. The "empty" spool not having been pushed fully out of the first receptacle, continues to move round with the first receptacle, supported by the lower guide.

30

In the inhaler of the prior art whilst the spool magazine lies essentially in the same plane as the as the mouthpiece of the inhaler, the push rod acts on a spool in a perpendicular plane.

5 We have now found a novel form of medicament delivery device in which a push rod lies in essentially the same plane as the delivery orifice of the device and actuates the spool in a direction which is coaxial with the delivery orifice of the device. Thus when a plurality of spools are arranged radially in a magazine, such that the longitudinal axis of the spools lie in the same plane as the magazine and the spool
10 may be expressed radially from the magazine. This has the advantage that, *inter alia*, a significantly slimmer device may be produced. Furthermore, the radial expression of the spools means that more than one magazine can be placed in the device and thus, *inter alia*, the device may deliver higher dosages, combination therapies and/or provide medication over a longer period of time.

15

Thus, according to the invention we provide a delivery device comprising a rotatable metering member adapted to dispense a measured amount of material, a material delivery passage and a material delivery orifice, and at least one actuator member adapted to move the metering member from a material retaining position to a
20 material dispensing position characterised in that the actuator member moves in a substantially radial direction and actuates the metering member in a substantially radial direction.

The device of the invention has utility in a variety of areas, including, for example,
25 medicament delivery. Thus, it is especially suited as an inhaler and especially a dry power inhaler (DPI).

According to a preferred feature of the invention the device is provided with a plurality of metering members housed in a magazine, preferably a substantially
30 circular magazine. In an especially preferred embodiment a plurality of magazines may be loaded into the delivery device of the invention, e.g. a pair of magazines.

When the metering member is in the medicament retaining position it is preferably out of communication with the inhalation passage and whilst the metering member is in the medicament dispensing position it is preferably in communication with the inhalation passage.

5

The metering member is of such dimensions as to be able to pass into the inhalation passage. The metering member may comprise those described in WO 93/16748. Thus, in one embodiment the metering member may comprise a spool housed in a spool carrier. The spool carrier acts as a conduit for the spool to communicate with the inhalation passage. Thus the spool will be provided with a flange at each end such that the flanges are in sealing engagement with the inner walls of the conduit and a space exists between the inner walls of the conduit and the non-flanged portion of the spool. In the filled metering member, the space is taken up by a measured dosage of medicament. Indeed, the plug, flanges and conduit are so dimensioned so as to predetermine the amount of medicament available. In an alternative embodiment of the invention the metering member may comprise a medicament container with a closed end and an open end, a cap adapted to abut the open end of the container and a sleeve adapted to overlap the open end of the container and the cap. Reference hereinafter to a spool and spool carrier is intended to encompass a capped cartridge as hereinbefore described.

20

The spool and spool carrier is generally that described in the prior art patent application. However, instead of the spool being mounted in a vertical position each spool is essentially horizontally mounted. For the sake of clarity, the spools are positioned in the same plane as the plane of the disc magazine. The push rod used to eject the spool from the spool carrier therefore operates radially from the centre of the disc and does not push the spool out of the disc plane.

25

The actuator member may comprise a push rod mechanism which may be substantially similar to that known conventionally save that it acts radially.

30

Alternatively, when a plurality of magazines is used the actuator member may, for example, comprise a pair of push rods.

As hereinbefore described a significant advantage of the device of the invention is
5 that it can be used to deliver combination therapies if desirable.

Increasingly, patients are required to take more than one medicine and this is no less the case in the treatment of bronchial disorders. Thus, for example, combination therapies such as a steroid with a β_2 agonist, eg fluticasone and salmeterol, have been
10 commercially successful. To date, the administration of such combination therapies comprises the use of a predetermined formulation either as a dry powder, eg in a gelatine capsule or a foil blister; or alternatively as a metered dose aerosol. However, this approach suffers from the disadvantage, inter alia, that the medical practitioner is restricted in that it is not possible to vary the quantities of the two
15 medicaments administered. Thus, there has therefore been a long felt need for a dry powder inhalation system which permits the administration of combination therapies.

It is within the scope of this invention for more than two medicaments to be administered, however, it is considered most likely that dual combination therapies
20 would be preferred by the medical profession. Thus the description hereinafter will generally refer to an inhaler adapted to administer a dual combination medicament, but it would be well understood by one skilled in the art that these references could be construed to multiple combinations.

25 Thus according to a further feature of the invention we provide a dry powder inhaler as hereinbefore described characterised in that the inhaler is adapted to take a plurality of disc magazines. The medicament encapsulated in the spool carriers of the two disc magazines may be the same or different. In one embodiment the medicaments are different and thus the inhaler is used to deliver a combination
30 therapy. Alternatively, the medicament encapsulated by the spool carrier may itself be a combination therapy.

In a further embodiment of the invention a medicament delivery device, eg an inhaler, comprises a pair of disc magazines. Such a device may preferentially be provided with means for engaging a first magazine whilst disengaging a second magazine and which is moveable from an engaging to a disengaging position and vice-versa.

Such means may comprise male and female interlocking members. Preferentially, the disc magazine is provided with a female member and a drive means is provided with a male member.

In an especially preferred embodiment a drive plate is provided with a male member and is adapted to engage with the drive means.

The male member may comprise a resilient protrusion which is resiliently biased towards a second disc magazine, but is constructed so as to be urged to engage with a female member of a first disc magazine, such that when the urging means is removed the male member is biased towards and engages with the second magazine.

A variety of medicaments may be administered by using the inhaler of the invention, such medicaments may have a systemic or non-systemic activity on the patient. Such medicaments are generally (but not limiting) antibiotics, bronchodilators or other anti-asthma drugs. Such medicaments include, but are not limited to β_2 -agonists, e.g. fenoterol, formoterol, pirbuterol, reproterol, rimiterol, salbutamol, salmeterol and terbutaline; non-selective beta-stimulants such as isoprenaline; xanthine bronchodilators, e.g. theophylline, aminophylline and choline theophyllinate; anticholinergics, e.g. ipratropium bromide; mast cell stabilisers, e.g. sodium cromoglycate and ketotifen; bronchial anti-inflammatory agents, e.g. nedocromil sodium; and steroids, e.g. beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations thereof.

Specific combinations of medicaments which may be mentioned include combinations of steroids, such as, beclomethasone dipropionate, fluticasone, budesonide and flunisolide; and combinations of two β_2 -agonists, such as, formoterol and salmeterol. It is also within the scope of this invention to include combinations
5 of one or more of the aforementioned steroids with one or more of the aforementioned β_2 -agonists.

Further medicaments which may be mentioned include systemically active materials, such as, proteinaceous compounds and/or macromolecules, for example, hormones
10 and mediators, such as insulin, human growth hormone, leuprolide and alpha interferon; growth factors, anticoagulants, immunomodulators, cytokines and nucleic acids.

When dual disc magazines are used the inhaler will be provided with two radially
15 acting push rod mechanisms. These mechanisms may be adapted to operate together, independently or sequentially.

The invention will now be illustrated by way of example only and with reference to the accompanying drawings, in which:

20

Figure 1 is a cross-sectional view of a spool and spool carrier;

Figure 2 is a perspective view of a single disc magazine comprising spools;

Figure 3 is a schematic representation of the ejection of a spool from the spool carrier;

25

Figure 4 is a perspective view of a combination therapy disc magazine; and

Figure 5 is a cross-sectional view of the combination therapy mechanism.

Figure 6 is a perspective view of a disc magazine provided with an empty spool holder;

30

Figure 7 is a perspective view of a pair of disc magazines provided with a drive plate;

Figure 8 is a schematic representation of a pair of magazines provided with a drive plate;

Figure 9 is a schematic representation of the carousel in operation with dual plunger rods;

5 Figure 10 is a schematic representation of the device when the first (lower) carousel has completed a 360° rotation;

Figure 11 is a perspective view of an alternative embodiment of a drive disc;

Figure 12 is a perspective view of a pair of disc magazines with a drive disc;

10 Figure 13 is a schematic representation of a device in operation with a dual plunger rod; and

Figure 14 is a schematic representation of a device when the first (lower) carousel has completed a 360° rotation.

With reference to Figure 1. A single medicament dose unit (1) is comprised of a
15 spool (2), a spool carrier (3) and a single dose of medicament (4), for use in a dry powder inhaler. The spool (2) comprises a longitudinal body (5) and terminal flanges (6 and 7) at each end. The sides (8 and 9) of the flanges (6 and 7) form a seal and a tight slidable fit with the inner walls (10 and 11) of the spool carrier (3). The length of the spool (2) and the length of the spool carrier (3) are substantially the same.
20 Each flange is provided with an external face (12 and 13).

With reference to Figures 2 and 3. A plurality of spools (2) and carriers (3) are joined in a disc to form a magazine. The plurality of dose units (1) arranged radially around the circumference of the magazine (14). The inhalation device is provided
25 with a dispensing mechanism (not shown) and a push rod (15) which also acts radially. The push rod (15) when actuated operates in the radial plane of the magazine (14) ejecting a spool (2) radially from the spool carrier (3) into the inhalation passage (not shown). The spool (2) remains in the plane of the magazine (14) and the flange (7) remains in co-operation with the spool carrier (3) so that it can
30 move out of the inhalation passage upon rotation of the magazine (14).

With reference to Figures 4 and 5. A "double decker" arrangement is achieved by joining a first magazine (14) with a second magazine (16). The inhaler mechanism is provided with a first push rod (5) and a second push rod (17). The push rods may be actuated jointly, separately or sequentially optionally allowing medicament to be dispensed at the same time in the spool from the first magazine (14) as in the spool from the second magazine (16).

With reference to Figure 6, a spool carrier magazine (101) comprises a disc provided with a plurality of radially mounted spool carriers (102). Each of the spool carriers (102) (save for one) is provided with a spool (103). One of the spool carriers (104) is empty and is provided with a cut away portion (105).

With reference to Figure 7, a pair of spool carrier magazines (101a and 101b) are provided. A drive disc (106) comprises a substantially planar annular disc. The inner surface (107) of the drive disc (106) is provided with a plurality of teeth (108) which are adapted to engage with a drive means (not shown).

Adjacent to the periphery (109) of the drive disc (106), the disc is provided with an aperture (110) through which protrudes an out of plane resilient male member (111). The male member (111) is biased towards one of the magazines. By way of example only, the embodiment described is one in which the male member (111) is biased towards the uppermost magazine (101b), although it should be understood that the present application should be read to also encompass an embodiment in which the male member may be biased towards the other magazine (101a).

The drive disc (106) is positioned adjacent to the first magazine (101a) such that the male member (111) overlies the cut away portion (105) and the empty spool carrier (104). When the second magazine (101b) is positioned in place it is arranged such that a filled spool carrier (102) overlies the male member (111). The circumferential surface (112) rests against the male member (111) and urges it into an engaging position with the empty spool carrier (104).

Thus, in use, when the annular drive disc (106) is rotated, the male member (111) engages with the empty spool carrier (104) to rotate the first magazine (101a) whilst the second magazine (101b) is disengaged and therefore remains unmoved.

5

With reference to Figures 8-10, the assembly of the system is illustrated. Thus, the assembly (113) comprises a chassis (114) and the drive disc (106) is placed above the magazine (101a). The male member (111) is biased away from the magazine (101a) and therefore protrudes above the plane of the drive disc (106). The second upper
10 magazine (101b) is then positioned above the drive disc (106).

The male member (111) comprises a substantially triangular shaped tab with a first surface (116), a second surface (117), a hinged end (118) and a distal end (119). Optionally, the hinged end (118) may be provided with a groove (119) to facilitate
15 the flexible movement of the male member (111). In its free position the male member (111) rests such that the first surface (116) lies in the plane of the drive disc (106) and the second surface (117) lies out of the plane and protrudes from the drive disc (111).

20 When the second, upper magazine (101b) is in place, the lower, outer surface (120) of the spool carrier magazine is urged against the second surface (117) of the male member (111). This urges the second surface (117) to lie in the plane of the drive disc (106) and therefore the first surface (116) lies out of the plane, enabling it to engage with the empty spool carrier (104).

25

A push rod (121) is also provided which comprises a pair of spool prodders (122a and 122b). The push rod (121) is connected to an actuator means (not shown). A chassis lid (114a) is provided to close the system.

30 With reference to Figures 11 to 14, a further embodiment is illustrated in which the male member (111a) protrudes beyond the peripheral edge (123) of the drive disc

(106). The chassis (114a) is provided with two sets of guide rails (124 and 125). The device is assembled so that the male member (111a) is tensioned and the peripheral end (126) of the male member (111) held in the guide rail (124). When the lower magazine has rotated through approximately 360° , the male member (111a) reaches a break in the guide rails (124 and 125), thus allowing the male member (111a) to be urged towards the second magazine and into the second guide rail (125).

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CLAIMS

1. A delivery device comprising a rotatable metering member adapted to dispense a measured amount of material, a material delivery passage and a material delivery orifice, and at least one actuator member adapted to move the metering member from a material retaining position to a material dispensing position characterised in that the actuator member moves in a substantially radial direction and actuates the metering member in a substantially radial direction.
5
- 10 2. A delivery device according to claim 1 characterised in that the device comprises a plurality of metering members adapted to dispense a measured amount of material, said metering members being held in a rotatable magazine.
- 15 3. A delivery device according to claim 2 characterised in that the device is adapted to take a plurality of magazines.
4. A delivery device comprising a plurality of rotatable magazines, each magazine being provided with a plurality of metering members adapted to dispense a measured amount of material, a material delivery passage and a material delivery orifice, and at least one push rod adapted to move a metering member from a material retaining position to a material dispensing position.
20
5. A delivery device according to claims 1 or 4 characterised in that the material is a medicament.
25
6. A delivery device according to claims 1 or 4 characterised in that the material is a dry powder.
7. A delivery device according to claims 2 or 4 characterised in that the magazine is substantially circular.
30

8. A delivery device according to claims 3 or 4 characterised in that the device comprises a pair of magazines.
- 5 9. A delivery device according to claim 8 characterised in that the device is provided with means for engaging a first magazine whilst disengaging a second magazine and which engaging means is moveable from an engaging to a disengaging position and vice-versa.
- 10 10. A delivery device according to claim 9 characterised in that the engaging means comprises male and female interlocking members.
11. A delivery device according to claim 10 characterised in that the magazine is provided with a female member and a drive means is provided with a male member.
- 15 12. A delivery device according to claim 11 characterised in that a drive plate is provided with a male member and is adapted to engage with the drive means.
- 20 13. A delivery device according to claim 12 characterised in that the male member comprises a resilient protrusion which is resiliently biased towards a second magazine, but is constructed so as to be urged to engage with a female member of a first disc magazine, such that when the urging means is removed the male member is biased towards and engages with the second magazine.
- 25 14. A delivery device according to claim 13 characterised in that the actuator means comprises at least two radially acting push rod mechanisms which may operate together, independently or sequentially.

15. A delivery device according to Claim 5 characterised in that the medicament metering member comprises a spool and a spool carrier wherein the void between the spool carrier is filled with medicament.
- 5 16. A delivery device according to Claim 15 characterised in that the device is provided with a pair of magazines and said pair of magazines contain the same medicament.
- 10 17. A delivery device according to Claim 15 characterised in that the device is provided with a pair of magazines and said pair of magazines contain different medicaments.
- 15 18. A delivery device according to claim 5 characterised in that the medicament delivery device is an inhaler
19. A delivery device according to claim 2 characterised in that the inhaler is a dry powder inhaler.
- 20 20. A dry powder inhaler comprising a metering member adapted to dispense a measured amount of medicament, an inhalation passage and a mouthpiece, and at least one push rod adapted to move the metering member from a medicament retaining position to a medicament dispensing position characterised in that the push rod moves in a essentially substantially radial direction and actuates the metering member in a substantially radial direction.
- 25 21. A dry powder inhaler comprising a plurality of metering members adapted to dispense a measured amount of medicament and held in a rotatable magazine, an inhalation passage and a mouthpiece, and at least one push rod adapted to move one of the plurality of metering members from a medicament retaining position to
- 30 a medicament dispensing position.

22. A dry powder inhaler according to Claim 17 characterised in that the medicaments are fluticasone and salmeterol.
23. A dry powder inhaler according to Claim 21 characterised in that the inhaler is
5 provided with two push rods.
24. A magazine comprising a plurality of radially mounted and radially facing spools said spools containing a medicament in dry powder form.
- 10 25. A magazines according to claim 24 characterised in that the magazine is coupled to a second magazine and is provided with an intermediate drive disc.
26. A method of delivering a material which comprises using a delivery device according to Claim 1.
15
27. A method of administering a dry powder medicament using a delivery device according to Claim 6.
28. A method according to claim 27 characterised in that a combination of
20 medicaments are administered.
29. A method of treatment of a patient with a respiratory disorder comprising the administration of a therapeutically effective amount of a medicament using an inhaler according to claim 18.
25
30. The use of salmeterol and/or fluticasone in the manufacture of an inhaler according to claims 1 or 2.
31. The use of salmeterol and/or fluticasone in the manufacture of a magazine
30 according to claims 24 or 25.

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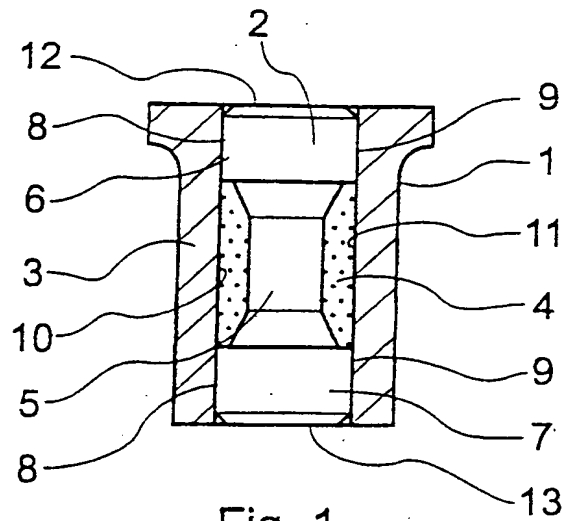


Fig. 1

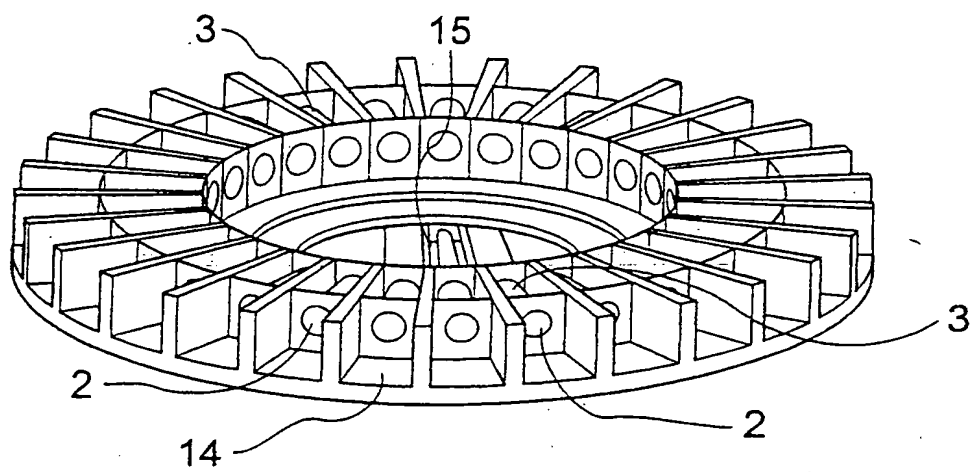


Fig. 2

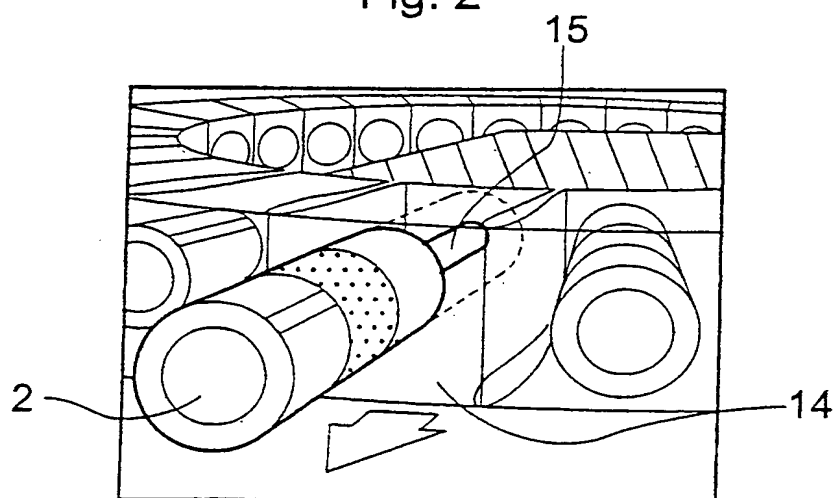


Fig. 3

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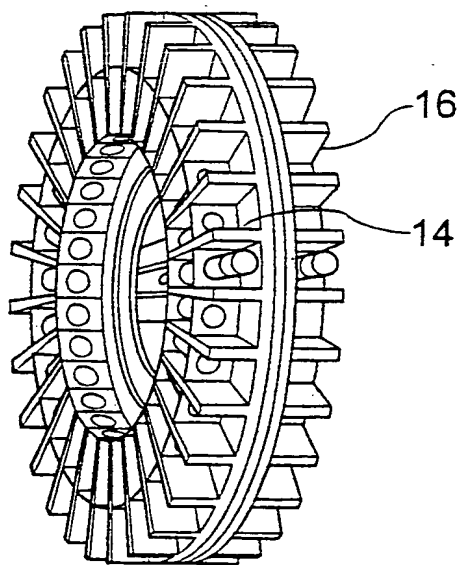


Fig. 4a

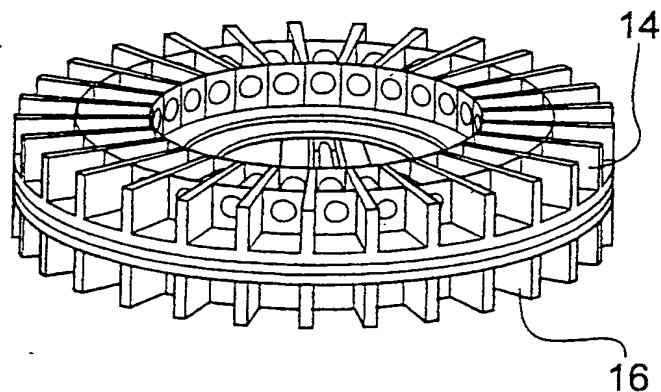


Fig. 4b

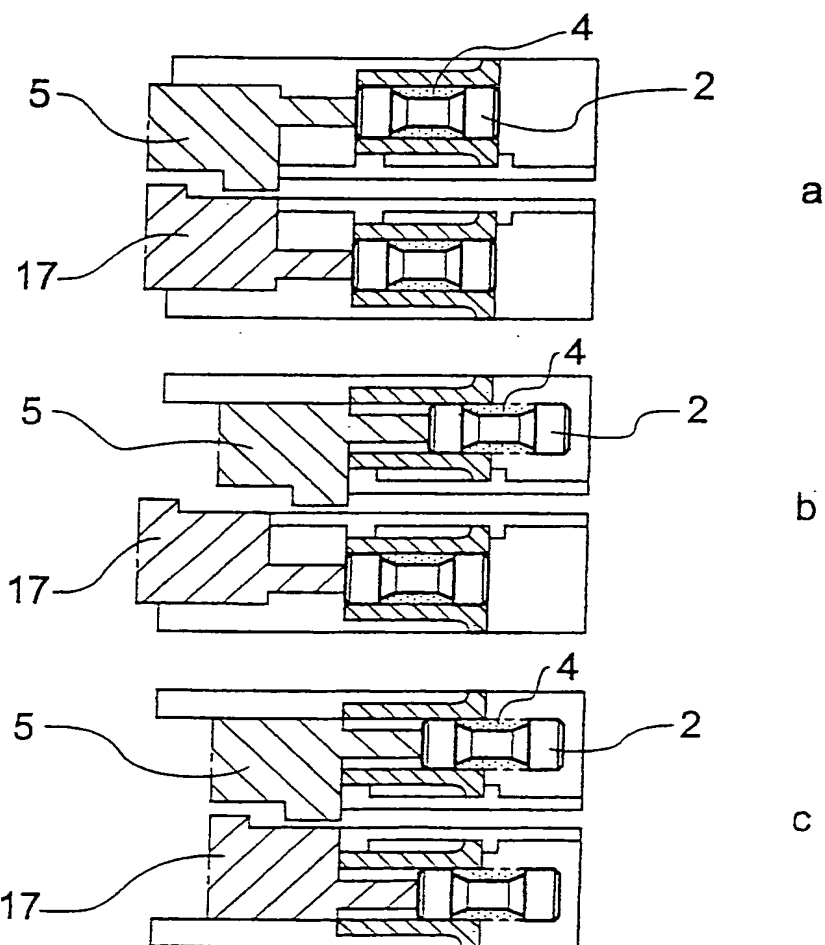


Fig. 5

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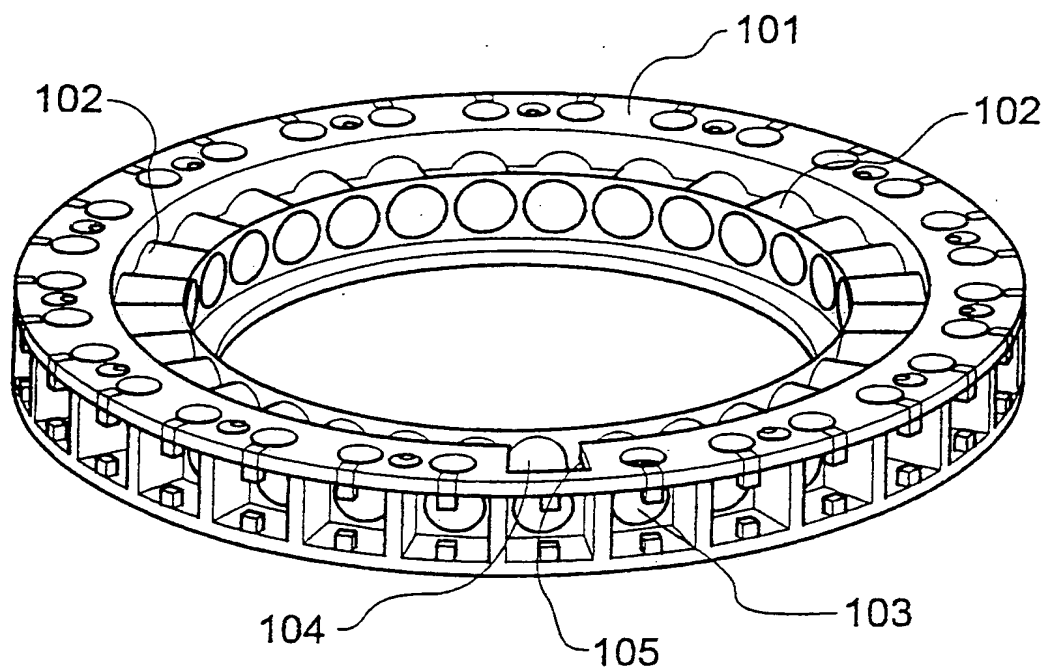


Fig. 6

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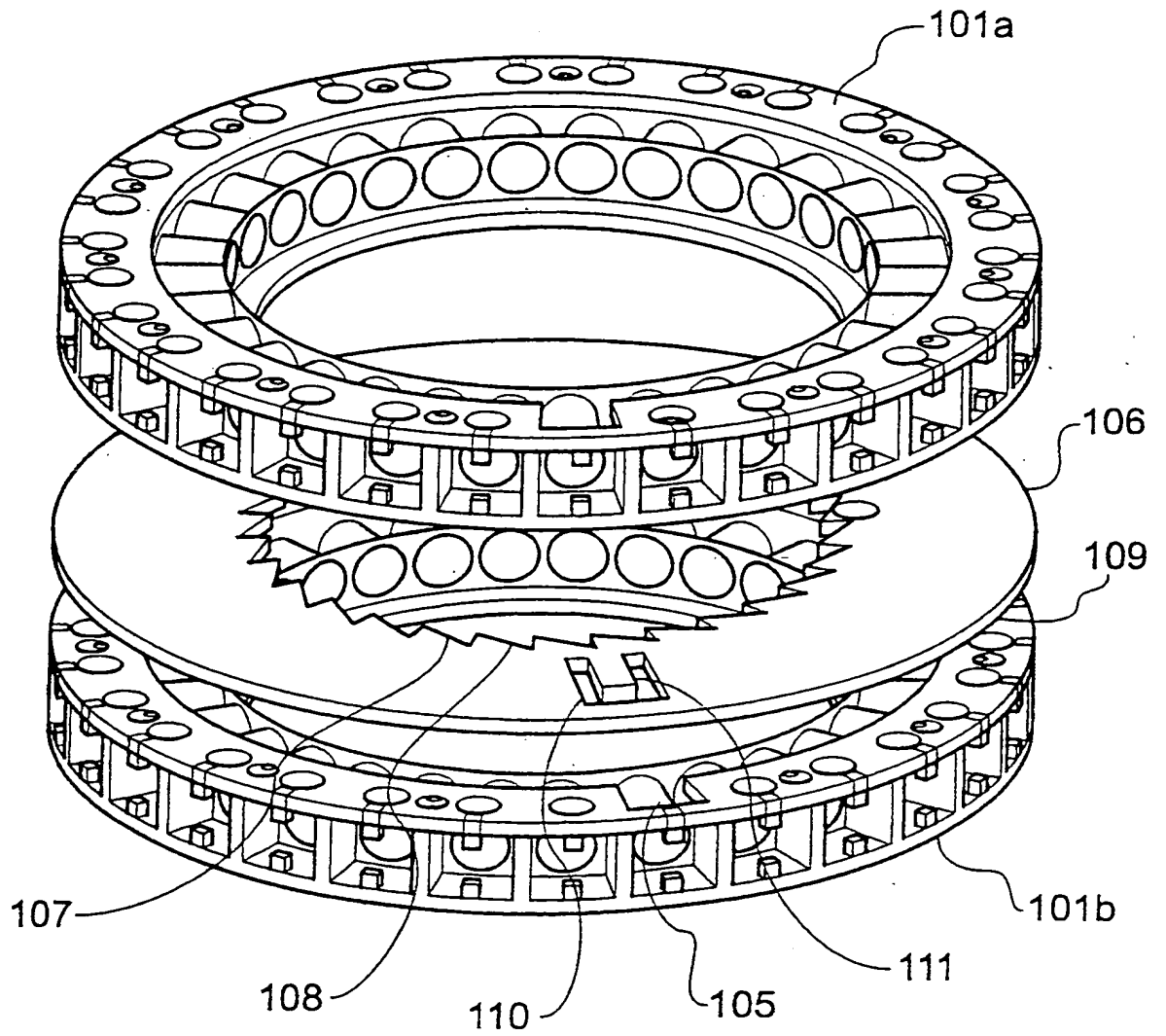


Fig. 7

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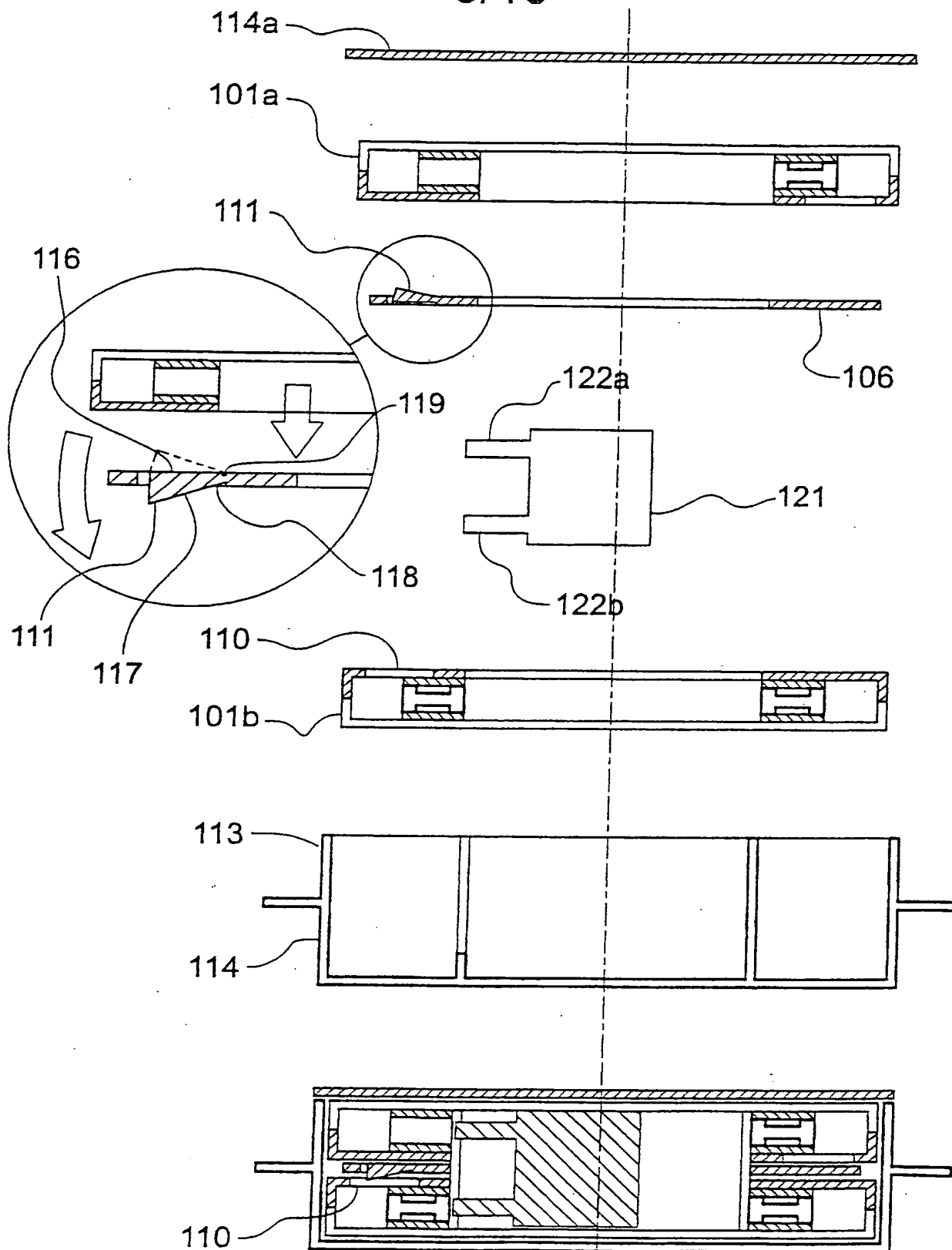


Fig. 8

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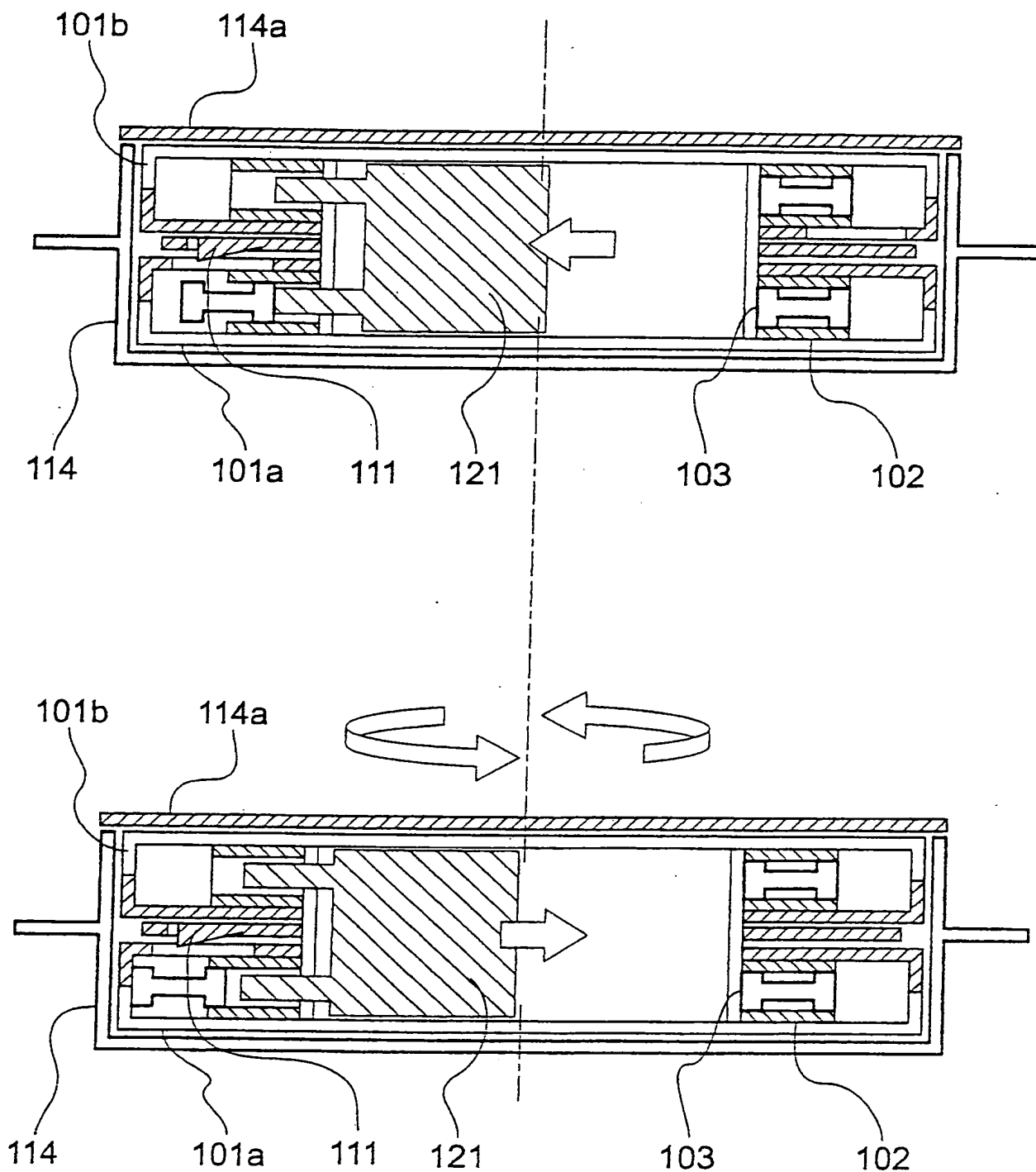


Fig.9

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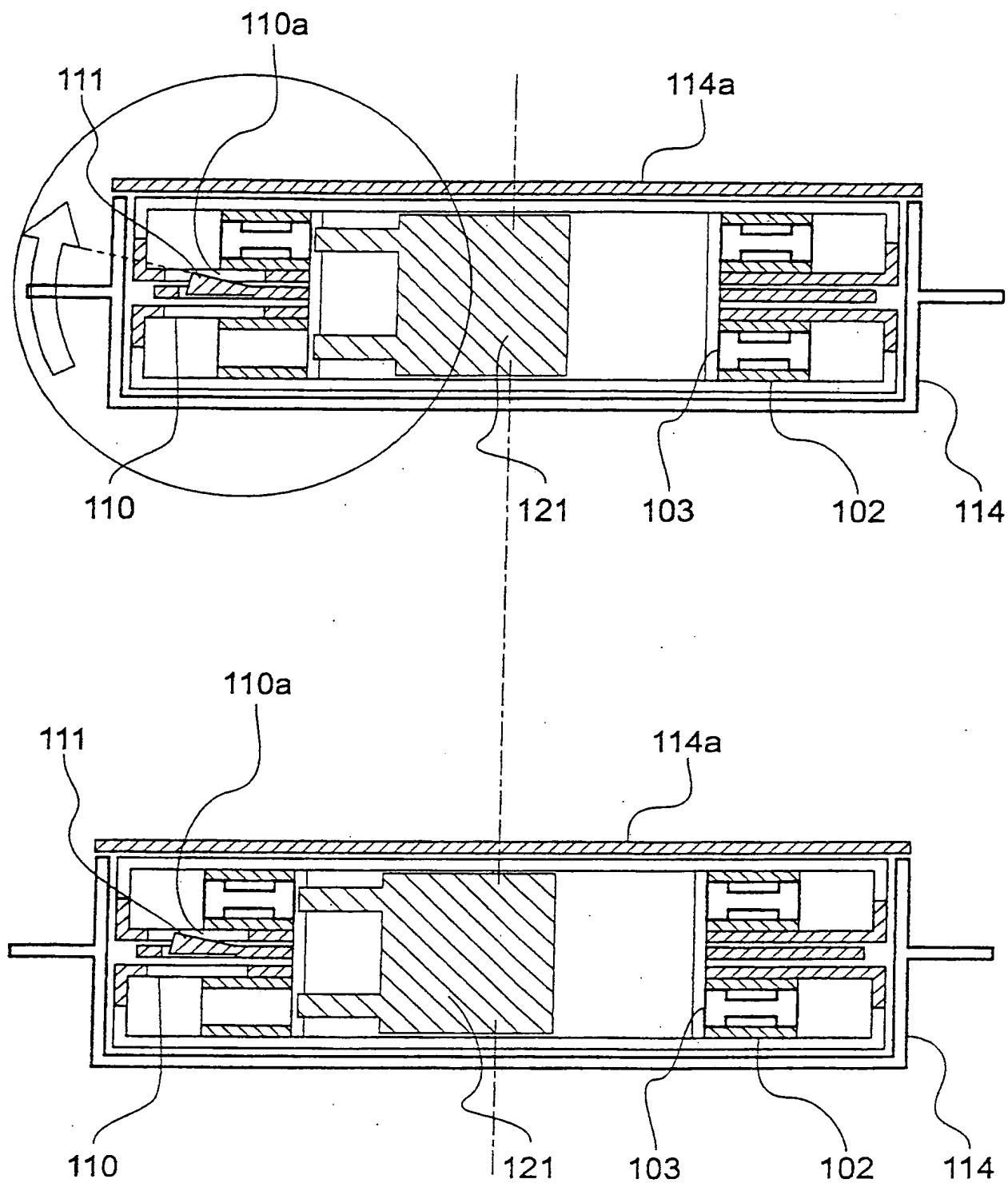


Fig.10

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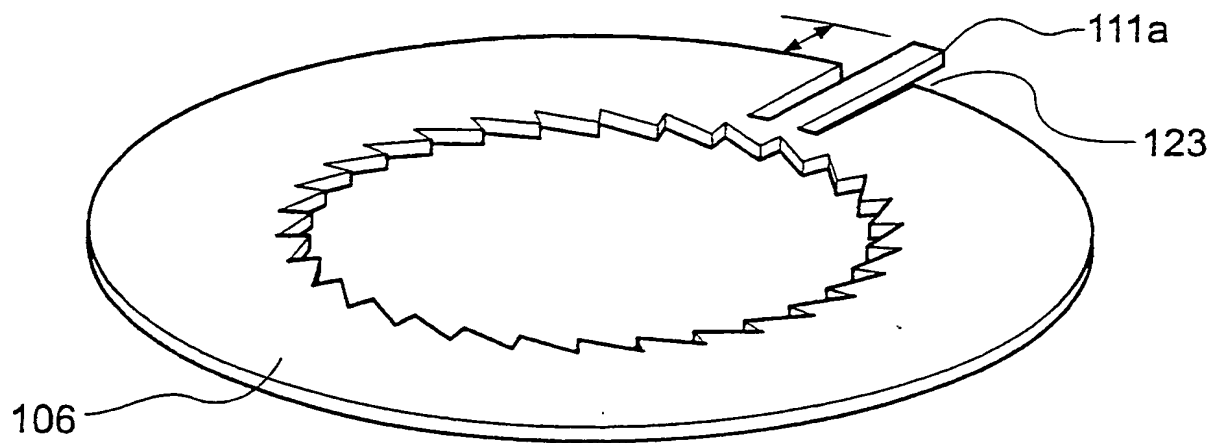


Fig. 11

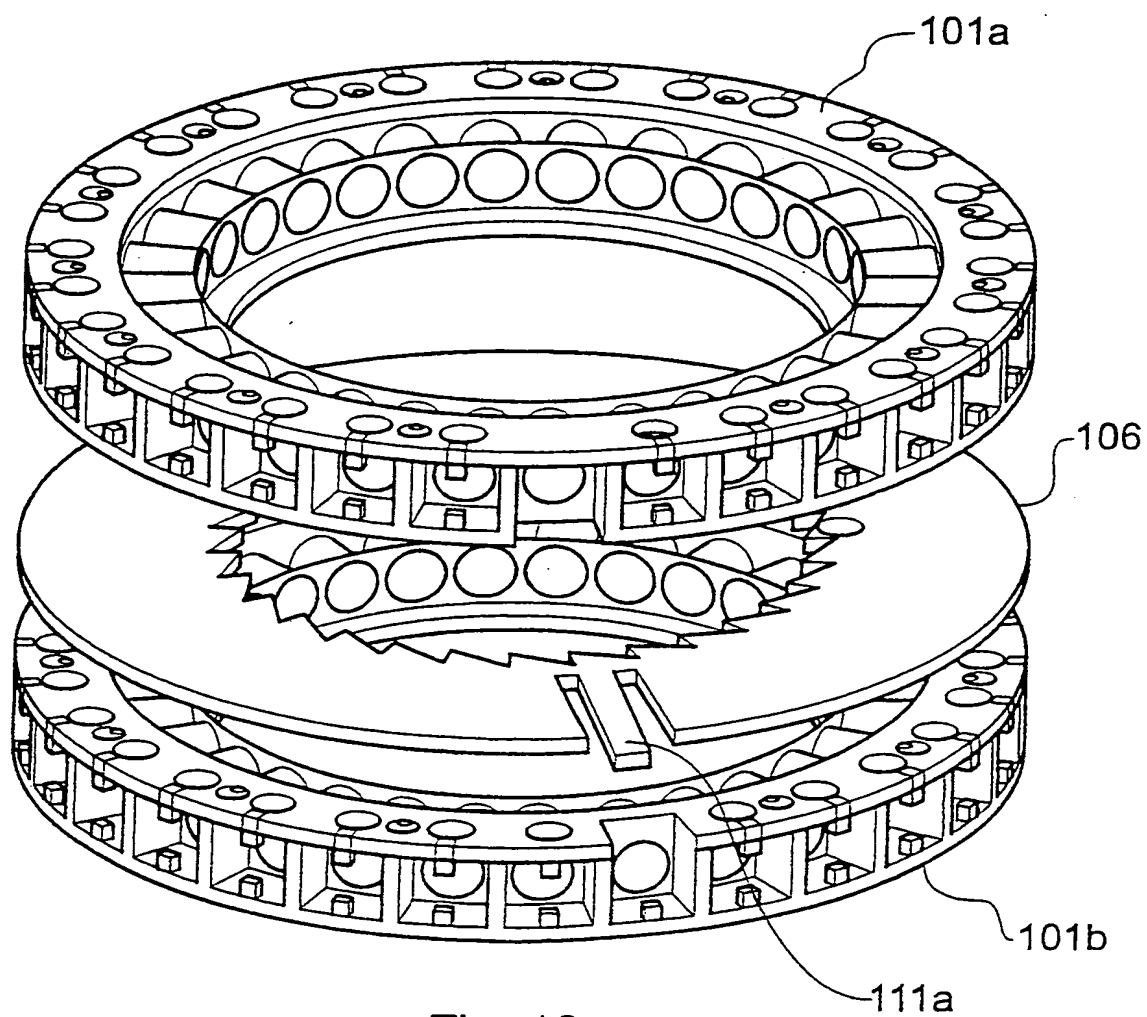


Fig. 12

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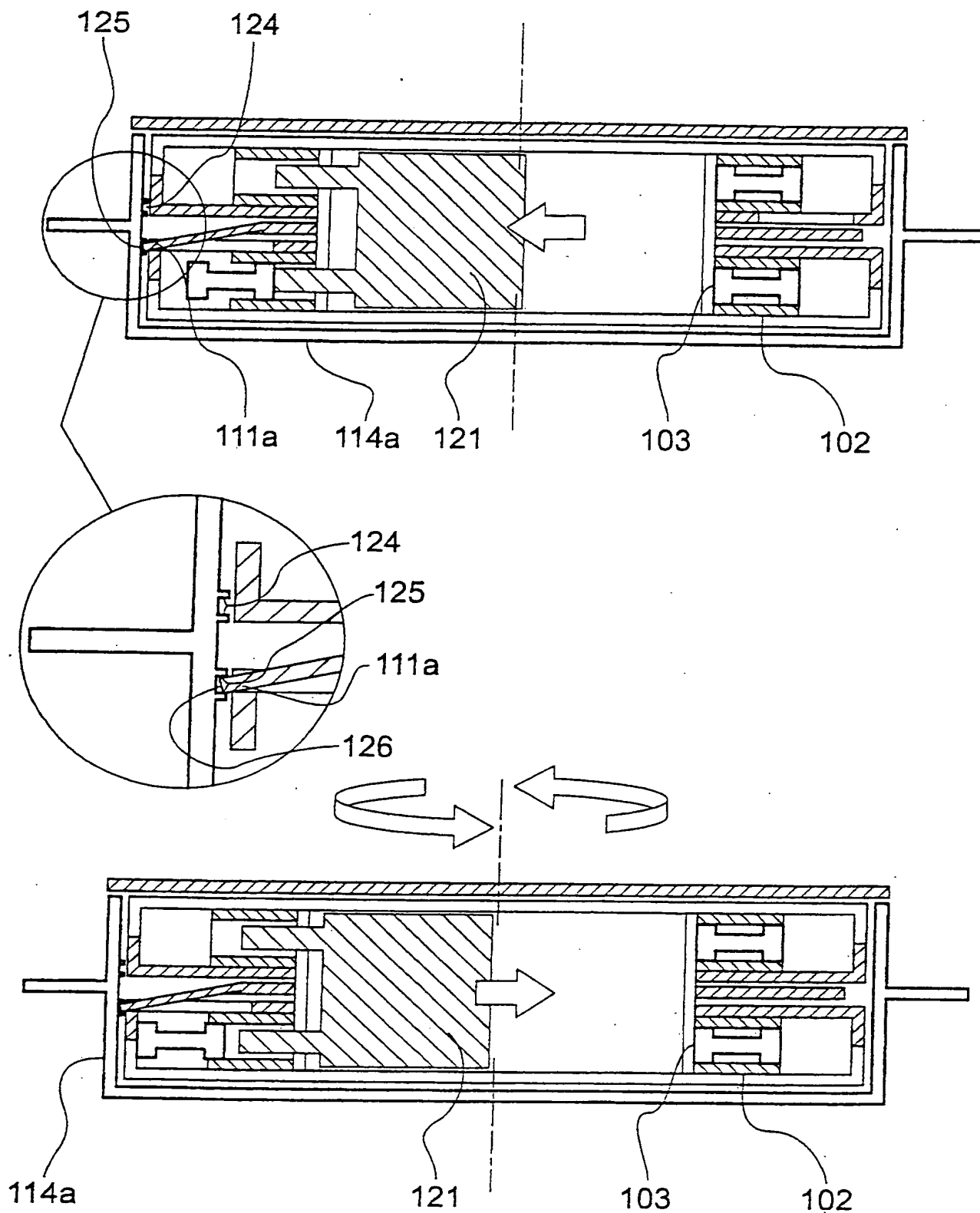


Fig.13

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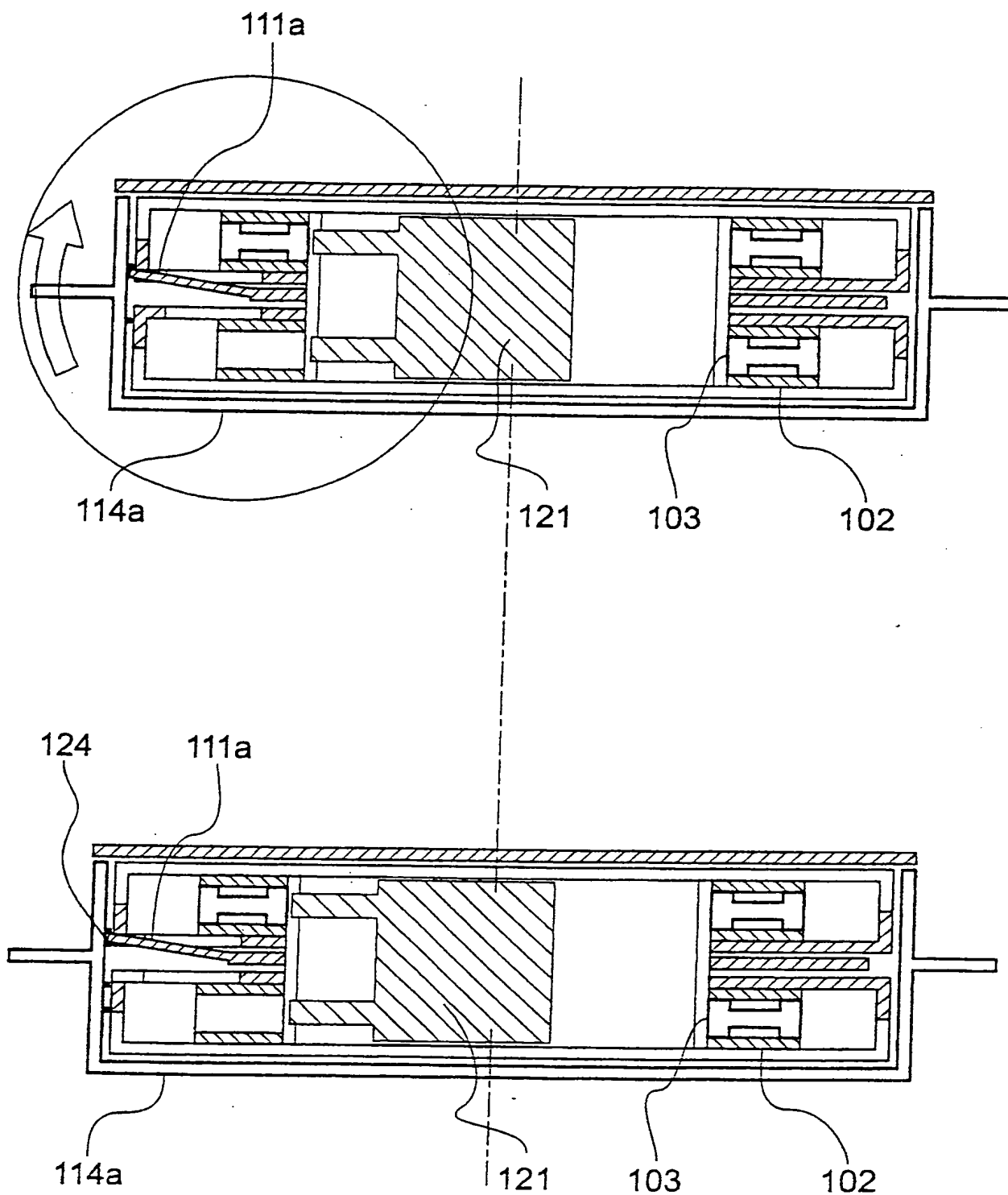


Fig.14

32. A delivery device substantially as described with reference to the accompanying drawings.

5

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International Application No

PCT/GB 00/03377

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International Application No

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 32

P.C.T. Rule 6.2 (a)

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

FURTHER INFORMATION CONTINUED FROM PCT/SA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3, 5-19, 20, 22, 30

Delivery device with radial actuator

2. Claims: 4-18, 21-23

Delivery device with a plurality of magazines

3. Claims: 24, 25, 31

A magazine comprising spools

INTERNATIONAL SEARCH REPORT

National Application No

GB 00/03377

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	claim 1; figures	3,15
Y	US 4 811 731 A (NEWELL ROBERT E ET AL) 14 March 1989 (1989-03-14)	3
A	column 7, paragraph 2; figures 10-12	4
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Y	WO 93 16748 A (INNOVATA BIOMED LTD) 2 September 1993 (1993-09-02) cited in the application claims; figures	15,24,31
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☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

20 December 2000

Date of mailing of the international search report

05/01/2001

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Fax: (+31-70) 340-3016

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Villeneuve, J-M

INTERNATIONAL SEARCH REPORT

nal Application No

PCT/GB 00/03377

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	abstract; figures 24-26 ---	1
A	US 5 301 666 A (LERK COENRAAD ET AL) 12 April 1994 (1994-04-12) claims 1,4-6; figures ---	8-12
A	US 5 415 162 A (BOUNDY MARYANNE G ET AL) 16 May 1995 (1995-05-16) ---	
X	US 5 896 855 A (COOK ROBERT S ET AL) 27 April 1999 (1999-04-27) claims 13-20 -----	1,2,5-7, 18-22,30

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Commissioner
 US Department of Commerce
 United States Patent and Trademark
 Office, PCT
 2011 South Clark Place Room
 CP2/5C24
 Arlington, VA 22202
 ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 21 May 2001 (21.05.01)	Applicant's or agent's file reference SPG/P36102WO
International application No. PCT/GB00/03377	Priority date (day/month/year) 04 September 1999 (04.09.99)
International filing date (day/month/year) 04 September 2000 (04.09.00)	
Applicant BRAITHWAITE, Philip	

1. The designated Office is hereby notified of its election made:

☒

in the demand filed with the International Preliminary Examining Authority on:

02 April 2001 (02.04.01)

☐

in a notice effecting later election filed with the International Bureau on:

2. The election
- ☒
- was

☐

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	Authorized officer Olivia TEFY Telephone No.: (41-22) 338.83.38
--	--

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PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference SPG/P36102W0	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 00/ 03377	International filing date (day/month/year) 04/09/2000	(Earliest) Priority Date (day/month/year) 04/09/1999
Applicant INNOVATA BIOMED LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

DELIVERY DEVICE

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☒ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

2

☐ None of the figures.

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-3, 5-19, 20, 22, 30

Delivery device with radial actuator

2. Claims: 4-18, 21-23

Delivery device with a plurality of magazines

3. Claims: 24, 25, 31

A magazine comprising spools

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 32

P.C.T. Rule 6.2 (a)

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

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INTERNATIONAL SEARCH REPORT

International Application No

P B 00/03377

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 03175 A (FISONS PLC) 5 March 1992 (1992-03-05)	1, 2, 4-7, 18-22, 30
Y	claim 1; figures	3, 15
Y	US 4 811 731 A (NEWELL ROBERT E ET AL) 14 March 1989 (1989-03-14)	3
A	column 7, paragraph 2; figures 10-12	4
X	US 4 860 740 A (KIRK WILLIAM F ET AL) 29 August 1989 (1989-08-29)	1, 2, 5-7, 18-22, 30
	claims 1-4; figures	
Y	WO 93 16748 A (INNOVATA BIOMED LTD) 2 September 1993 (1993-09-02)	15, 24, 31
	cited in the application	
	claims; figures	
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

Date of the actual completion of the international search

20 December 2000

Date of mailing of the international search report

05/01/2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Villeneuve, J-M

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INTERNATIONAL SEARCH REPORT

International Application No

P B 00/03377

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	✓ US 5 562 918 A (STIMPSON PHILIP G) 8 October 1996 (1996-10-08)	24, 31
A	abstract; figures 24-26 ---	1
A	✓ US 5 301 666 A (LERK COENRAAD ET AL) 12 April 1994 (1994-04-12)	8-12
	claims 1,4-6; figures ---	
A	✓ US 5 415 162 A (BOUNDY MARYANNE G ET AL) 16 May 1995 (1995-05-16)	

X	✓ US 5 896 855 A (COOK ROBERT S ET AL) 27 April 1999 (1999-04-27)	1,2,5-7, 18-22,30
	claims 13-20 -----	

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

P B 00/03377

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9203175	A	05-03-1992	NONE	
US 4811731	A	14-03-1989	AT 396872 B	27-12-1993
			AT 204086 A	15-05-1993
			AU 591152 B	30-11-1989
			AU 6065586 A	12-02-1987
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			GR 861995 A	04-11-1986
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			IE 59026 B	15-12-1993
			IL 79550 A	10-06-1991
			IT 1195984 B	03-11-1988
			JP 1871546 C	06-09-1994
			JP 62041668 A	23-02-1987
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			KE 3865 A	19-05-1989
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			PT 83094 A,B	26-01-1987
			SE 8603252 A	31-01-1987
			SG 8789 G	07-07-1989
			US 5035237 A	30-07-1991
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			AU 554502 B	21-08-1986
			AU 7893381 A	21-05-1982
			BE 890937 A	30-04-1982
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			CA 1169322 A	19-06-1984
			DE 3174779 D	10-07-1986
			DK 293882 A,B,	30-06-1982
			EP 0063599 A	03-11-1982
			ES 506585 D	01-09-1982
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			FI 76258 B	30-06-1988
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/JP 00/03377

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		MX 157953 A	28-12-1988
		NO 822300 A,B,	30-06-1982
		NZ 198822 A	30-04-1985
		PT 73899 A,B	01-11-1981
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		ZA 8107513 A	25-05-1983
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		AU 3508793 A	13-09-1993
		BR 9305942 A	21-10-1997
		CA 2130477 A	02-09-1993
		CN 1082191 A,B	16-02-1994
		CN 1234280 A	10-11-1999
		DE 69328358 D	18-05-2000
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		EP 0626869 A	07-12-1994
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		ES 2145770 T	16-07-2000
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		DE 69318027 D	20-05-1998
		DE 69318027 T	13-08-1998
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		JP 8500750 T	30-01-1996
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		CN 1074381 A	21-07-1993
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		JP 5245201 A	24-09-1993
		KR 218816 B	01-10-1999
		ZA 9209232 A	26-05-1993
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		AU 5710294 A	19-07-1994
		CA 2152168 A	07-07-1994

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

P/B 00/03377

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5896855 A		DE 69317302 D	09-04-1998
		DE 69317302 T	20-08-1998
		DK 675742 T	28-09-1998
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		ES 2115923 T	01-07-1998
		WO 9414491 A	07-07-1994
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		JP 8504634 T	21-05-1996
		MX 9400086 A	29-07-1994
		ZA 9309705 A	29-08-1994

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PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Harrison Goddard Foote
Tower House
Merrion Way
Leeds LS2 8PA
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
(day/month/year)

04.12.2001

Applicant's or agent's file reference
SPG/P36102WO

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/03377

International filing date (day/month/year)
04/09/2000

Priority date (day/month/year)
04/09/1999

Applicant
INNOVATA BIOMED LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
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Authorized officer

Terzic, K

Tel. +49 89 2399-2052



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SPG/P36102WO	FOR FURTHER ACTION		See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/03377	International filing date (day/month/year) 04/09/2000	Priority date (day/month/year) 04/09/1999	
International Patent Classification (IPC) or national classification and IPC A61M15/00			
Applicant INNOVATA BIOMED LIMITED et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 14 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input checked="" type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input checked="" type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 02/04/2001	Date of completion of this report 04.12.2001
Name and mailing address of the international preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 </div> </div>	Authorized officer Krantz, L Telephone No. +49 89 2399 2523



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03377

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-10 as originally filed

Claims, No.:

1-32 as originally filed

Drawings, sheets:

1/10-10/10 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03377

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
☐ paid additional fees.
☐ paid additional fees under protest.
☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
☒ the parts relating to claims Nos. 1 - 3.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims
	No: Claims 1 , 2 .
Inventive step (IS)	Yes: Claims
	No: Claims 1 , 2

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03377

Industrial applicability (IA) Yes: Claims 1 , 2
 No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

International application No. PCT/GB00/03377

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03377

The following documents cited in the International Search report will be referred to by means of the following appellation:

D1 : WO-A-92-3175

D2 : US-A-4 860 740

IV

Lack of unity :

The application is considered to claim (at least) two inventions :

Claim 1 defines a delivery-device where some metering-members containing an unknown material , rotate but are not necessarily in a magazine.

Independent claim 24 defines a magazine for some spools containing medicine. Thus the magazine of claim 24 does not contain metering-members but spools which may have another form than metering-members. Furthermore the magazine may not be able to be used with the delivery-device of claim 1 , the magazine may have nothing to do with the delivery-device of claim 1 which may be for cement.

Further proofs for lack of unity under PCT-Rule 13 will be given below.

The reason that the examining-division mentions a lower number of independent inventions than the search-division is that some of the independent claims are considered to be so far away from the description , that they lack support in the description , Article 6 PCT and should be deleted.

Yet this may not prevent a search for such constructions.

IV .2

General comment about lack of unity according to PCT-Rule 13 :

If an Applicant wishes to define his invention in several independent claims

Rule 13 requests that there are some features IN COMMON

between ALL independent claims (see also PCT-Guidelines C-III 4.4 :

ANY independent claim should contain ALL essential features)

and these features have to be novel.

Since the subject-matter of claim 1 is not new (see below) there is not one single new feature in claim 1 which could possibly be in common with other independent claims.

Also independent claim 24 lacks novelty , see below.

V

Claim 1 is not new over D1:

In D1 the metering-members are the capsules C positioned in a rotating magazine 4.

The rotation-axis of this magazine 4 is the cylindrical shaft 26 on which the magazine 4 is mounted see D1 page 7 line 6.

In D1 fig 1 the capsules C (= metering-member) fall down through hole 40 into a chamber see also D1 fig 2 near 8.

From this chamber the capsule is pushed horizontally by pushing-portion 56 into the center-chamber 12 (capsule emptying chamber 12 , P.6 L.24) and punctured by horizontally moving pins 60.

Thus the features of claim 1 of the invention are seen as follows in D1:

- rotatable metering-member C
- material delivery passage 26
- material delivery orifice 48 (mouthpiece 48)

→ →

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03377

- actuator member 56 , 64
(material retaining position D1 fig 2)
- the actuator-member 56 moves radially to the rotation-axis 26 of the magazine 4 and pierces the capsule C (metering-member) with two radial holes.

The capsules in D1 ALSO move between two planes , but this is also possible in claim 1 of the invention as long as the two radial "actions" are present.

V .2

Claim 1 also lacks novelty over D2:

In D2 fig 3-a the user or patient opens the cover 28 , 31.

Then in D2 fig 3-b the user presses on latch-42 which will free a ledge-44 on extractor-23.

Due to spring-40 (D2 fig 1) this extractor-23 will automatically move up as seen in D2 fig 3-c and thereby pull up the top-14 of a medicine-capsule 12-14.

In a second half of this upwards movement the pawl-41 on spring-40 (D2 fig 1) will push a toothed-wheel-36 (D2 fig 2) and thereby turn by one step the round support-member-20 which is the magazine for the capsules 12-14.

By this one-step rotation the open capsule 12 (where the top-14 has already been pulled off by extractor-23) is rotated into opening 19 leading to mouthpiece 18 , this is the situation in D2 fig 3-d.

Thus the features of claim 1 of the invention are seen as follows in D2:

- rotatable metering-member 12 - 14
- material delivery passage 19
- material delivery orifice 18 (mouthpiece 18)
- actuator member 23 + 40 + 41
(material retaining position D2 fig 3-b , the top-14 is still on
the capsule 12-14)
- the actuator-member 23 moves radially to the rotation-axis 22 of
the magazine 20 and actuates the capsule 12-14 (metering-member)
by pulling off the top-14 in a radial direction D2 fig 3-c

V .3

Also dependent claim 2 lack novelty over D2:

In D2 there are several capsules (metering-members) in
the rotating magazine 20.

V .4

Claim 3 is unclear. It is stated as a mere wish that the device can
take up to a million magazines without giving any constructional details.

V .5

Other claims:

Also independent claim 24 lacks novelty over D2:

If the capsules 12-14 in D2 are called spools (they can roll on a table just like the spools 2 of the invention) , they are radially mounted in magazine 20 in D2 and they are also radially "facing" ie. they will open in a radial direction and powder will come out in a radial direction, D2 fig 3-d. In a new claim for a magazine , it should be specified where the "face" of a spool is , otherwise it is not possible to determine if a spool is "facing" anything.

Claims 30 and 31:

It is considered obvious to use ANY available dry medicine in the device and magazines of D1 and D2.
(there is no INHALER in claims 1 or 2 as alleged in claim 30).

VII

Ambiguities or other problems in the claims :

In claim 1 first line "rotatable" should be rotatable ..

Claims 26 , 27 , 28 and 32 have not been searched and therefore will never be examined.

Claim 29 is not examined due to PCT-Rule 67.1.iv (therapy) .

The claims appended to each other should be grouped together see PCT-Rule 6.4.c

Therefore claim 19 should be moved forward near claim 2.

Claim 22 should be moved up after claim 17.

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The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Consistent terminology PCT-Rule 10.2 :

The same items should have the same names all over and not be called "spools" in some claims and "metering-members" in others. It is pointed out that infringement of a rule is sufficient to refuse an application in a national phase.

Independent claims being unclear or not supported by description :

Independent claim 4 is not supported by the description :

According to the description it is a basic principle of the invention that the device is FLAT , page 2 line 11:

"... a significantly slimmer device may be produced" .

This is obtained by letting the push-rod (moving the ampoules or metering-members or spools 2) move in the same plane as the other parts of the device , see page 2 line 6:

"... push rod lies in essentially the same plane ... axis of the spools lie in the same plane as the magazine"

All this is not in independent claim 4. Here the push-rod may be perpendicular to everything else in the device and does not move in any radial-direction as in claim 1.

Although the search-examiner has searched this claim namely devices with several magazines , the examining-division does not consider it justified that the Applicant (in a later national procedure) obtains protection for a device for which there is no embodiment given in the description . It is against PCT-Rule 5.1.a.v :

"The description shall ... set forth at least the best mode"

Therefore claims 5 - 18 , all appended to claim 4 , are not commented upon.

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Independent claim 20 is unclear.

If a man is told to walk in a RADIAL direction he naturally also will need information about where the CENTER (or rotation axis as in claim 1) is. There is no such information in claim 20, the metering-member is not even said to rotate.

Independent claim 21 is not supported by the description:

The problem is the same as in claim 4.

The push-rod may be perpendicular to anything else and although the magazine is said to rotate then the push-rod is not moving along a radius to the rotation-axis.

VII .2

Problems in the description:

The description should be adapted to new claims

Thus page 2 lines 15 - 22 are a word-by-word repetition of original claim 1.

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description nor are these documents identified therein.

Page 8 line 22 "uppermost magazine 101-b" actually magazine 101-b is DOWN in figure 7.

P.8 L.29 "circumferential surface 112" there is no number 112 in any figure.

P.9 L.8 "The male member 11 is biased away from the magazine 101-a ..."
In fig 9 the pin 11 points down into magazine 101-a.

P.9 L.13 119 is used for two different things a groove and a distal-end.

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The TITLE is not precise , PCT-Guidelines C-II 3.2

The title "device" does not give the public the slightest idea within which technical field the invention is (automobiles and toothbrushes are also devices)

It is noted that if the Applicant does not limit the claims to inhalators then additional searches may be necessary in a national phase.

See first lines of the description :

"This invention relates to a novel form of material delivery device ..."

This includes also rotating magazines for cement dispensers or for filling metered pouches of rice into food packages.

VII .3

The primary reason for lack of unity was given in the first communication to the Applicant of 19.7.2001 and is repeated in the present communication section IV and this reason necessitates NO comparison with prior art. Thus this reason belongs to "a priori" lack of unity according to the separation between "a priori" and "a posteriori" given in PCT-Guidelines C-III 7.5

According to PCT-Guidelines C-VI 5.3 iii the problem of lack of unity can be dealt with CONCURRENTLY with the first written opinion.

The first written opinion should deal with the relevant items under PCT-Rule 66.2.a (obviously not all of the items since amino-acids may not be present in all applications) .

In the first communication of 19.7.2001 ADDITIONALLY an extensive examination of novelty or clarity of several claims (claims 1 - 18 , 20 , 21 , 24 and 26 - 31) and of ambiguities in the description was given whereby the requirements of PCT-Rule 66.2.a for the contents of a first written opinion are met.

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Therefore a statement from the Applicant after the receipt of the first communication of 19.7.2001 that he looks forward to receive a written opinion cannot be complied with. Such a written opinion would not have had other contents than the first communication and thus would have been a superfluous repetition. With the first communication 19.7.2001 the Applicant received sufficiently information to reduce , restrict or amend the claims.

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